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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
1624	8

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,585	BRESLOW ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 14-32* is/are pending in the application.

4a) Of the above claim(s) *1* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14 and 19-32* is/are rejected.

7)☒ Claim(s) *15-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. This action is in response to amendments filed on 4/19/03. Applicant has amended claims 14 and 28. There are twenty claims pending and nineteen under consideration. Claims 14-18 are compound claims. Claims 19-27 are composition claims. Claims 28-32 are use claims. This is the second action on the merits. The application concerns some phthalocyanine compounds, compositions, and uses thereof.

Election/Restrictions

2. Applicant's election of Group II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claim 1 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

Response to Amendment

4. Applicants' amended abstract overcomes the objection made in point #8 of the previous office action. Applicants' amendment concerning "alkylene" overcomes the indefiniteness rejection made in point #10. Applicants' amendment to claim 28 overcomes the enablement rejection made in point #11.

Claim Rejections - 35 USC § 112

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 14 and 19-32 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants offer CO_2^-, $N^+(CH_3)_3$, and SO_3^- as possible variants for R_1. What counter ions are intended for these three charged radicals? The Examiner understands that the zinc ion has a formal +2 charge and that charge is balanced by the two formal –1 charges on two of the phthalocyanine nitrogen atoms. Therefore there is no balancing charge for the three charged substituents, *Ex parte Diamond* 123 USPQ 167.

Applicants argue that they are not required to specify what counter ions are associated with these three radicals. They also claim that the skilled organic chemist could ascertain what counter ions were intended. This is not persuasive for four reasons. First, the case cited above says otherwise. Secondly, in the previous action, the Examiner asked what counter ions were intended. If Applicants' cannot answer the question, then how id the public to understand the metes and bounds of the claimed subject matter. Thirdly, there are an infinite number of possible negatively charged and positively charged ions that could be intended. Are all of them presently claimed? Fourthly, As stated *In re Zletz*, 13

USPQ2d 1320, 1322, "An essential purpose of patent examination is to fashion claims that are precise, clear, correct and unambiguous." The lack of specified counter ion means that the skilled chemist could not understand the full limits of the claims, which are ambiguous.

6. Claims 28-32 remain rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for treating tumors generally. The specification does not enable any physician skilled in the art of medicine, to use the invention commensurate in scope with these claims. There are three grounds for making this rejection. Firstly, evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds *In re Buting* 163 USPQ 689.

Secondly, to make clearer the lack of enablement for treatment of all tumors, extrinsic evidence is supplied by Draetta (Ann. Reports Med. Chem.), final sentence on page 246 "Although many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely." Since no universal cure for cancer has been developed, it follows that there could

be no correlation between any chemical assays relied upon by Applicants and the ability to treat all cancers.

Thirdly, Lane (Sci. Amer.) reports in the fourth through the seventh paragraph on page 41 that photo therapy has not shown efficacy against all tumors. In the absence of any biological test data, why do Applicants feel their compounds will specifically target any specific tumor cell, let alone all tumor cells? The remarkable advances in chemotherapy have seen the development of specific compounds to treat specific types of cancer. The great diversity of diseases falling within the "tumor" category means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against such diseases. The intractability of these disorders is clear evidence that the skill level in this art is low relative to the difficulty of the task.

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546. a) Determining if any particular cancer would be treatable with

Applicants' compounds would require clinical trials in each separate cancer with each compound. Considering the hundreds of thousands of compounds covered by formula I and the multitude of different tumors, this is a very large degree of experimentation. b) The direction concerning cancer treatment is found in lines 15, page 18 to line 19, page 19, which merely states Applicants intention to do so. No specific types of cancer are mentioned. Applicants describe no *in vitro* or *in vivo* assays of their compounds concerning tumor treatment. Applicants describe no formulations, no doses, and no routes of administration required to practice their invention. Since no phthalocyanine photosensitizing molecule has ever shown clinical efficacy for cancer treatment, how is the skilled oncologist to understand what dose is to be used? c) There is no working example of tumor treatment in man or animal in the specification. d) The claims rejected are drawn to clinical medicine and are therefore physiological in nature. e) The state of the art in cancer therapy generally and in cancer photo therapy is summarized above. f) The artisan using Applicants invention would be a Board Certified physician in oncology with an MD degree and several years of experience. g) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166

USPQ 18, 24 (CCPA 1970). h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula I as well as the presently unknown list of tumors embraced by claim 28. Thus, the scope of the claim is broad.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice Applicants' invention.

Applicants argue that tumors are a more restricted set of diseases than cancers generally and further argue that they are not required to show efficacy against all tumors. Thus is not persuasive for three reasons. Firstly, according to Stedman there over two hundred such timorous conditions, including, "acinar cell tumors a solid and cystic tumors of the pancreas, occurring in young women; tumors cells contain zymogen granules. Acoustic tumors SYN: vestibular schwannoma. Acute splenic tumors acute splenitis, enlargement, and softening of the spleen, usually due to bacteremia or severe bacterial toxemia. Adenoid tumors

adenoma, or neoplasm with gland like spaces. Adenomatoid tumors a small benign tumors of the male epididymis and female genital tract, consisting of fibrous tissue or smooth muscle enclosing anastomosing gland-like spaces containing acid mucopolysaccharide lined by flattened cells that have ultra-structural characteristics of mesothelial cells. SYN: benign mesothelioma of genital tract tumors, adenomatoid odontogenic tumors a benign epithelial odontogenic tumors appearing radiographically as a well-circumscribed, radiolucent-radiopaque lesion usually surrounding the crown of an impacted tooth in an adolescent or young adult; characterized histologically by columnar cells organized in a duct like configuration interspersed with spindle-shaped cells and amyloidlike deposition that gradually undergoes dystrophic calcification. SYN: adenoameloblastoma, ameloblastic adenomatoid tumors. Adipose tumors SYN: lipoma. Ameloblastic adenomatoid tumors SYN: adenomatoid odontogenic tumors. amyloid tumors SYN: nodular amyloidosis. aortic body tumors SYN: chemodectoma. Bednar tumors SYN: pigmented dermatofibrosarcoma protuberans. benign tumors a tumors that does not form metastases and does not invade and destroy adjacent normal tissue. SYN: innocent tumors. blood tumors term sometimes used to denote an aneurysm, hemorrhagic cyst, or hematoma. borderline ovarian tumors an ovarian surface epithelial tumors in which the

growth pattern is intermediate between benign and malignant; includes mucinous, serous, endometrioid, and Brenner tumors of the ovary; highly curable but may recur after surgical removal. SYN: low malignant potential tumors. Brenner tumors a relatively infrequent benign neoplasm of the ovary, consisting chiefly of fibrous tissue that contains nests of cells resembling transitional type epithelium, as well as glandlike structures that contain mucin; origin is controversial, but it may arise from the Walthard cell rest; ordinarily found incidentally in ovaries removed for other reasons, especially in postmenopausal women. Brooke tumors SYN: trichoepithelioma. brown tumors a mass of fibrous tissue containing hemosiderin-pigmented macrophages and multinucleated giant cells, replacing and expanding part of a bone in primary hyperparathyroidism. tumors burden the total mass of tumors tissue carried by a patient with a malignancy. calcifying epithelial odontogenic tumors a benign epithelial odontogenic neoplasm derived from the stratum intermedium of the enamel organ; a painless, slowly growing, mixed radiolucent-radiopaque lesion characterized histologically by cords of polyhedral epithelial cells, deposits of amyloid, and spherical calcifications. SYN: Pindborg tumors. carcinoid tumors a usually small, slow-growing neoplasm composed of islands of rounded, oxyphilic, or spindle-shaped cells of medium size, with moderately small vesicular nuclei, and covered by intact mucosa with a yellow cut

surface; neoplastic cells are frequently palisaded at the periphery of the small groups, and the latter have a tendency to infiltrate surrounding tissue. Such neoplasms occur anywhere in the gastrointestinal tract (and in the lungs and other sites), with approximately 90% in the appendix and the remainder chiefly in the ileum, but also in the stomach, other parts of the small intestine, the colon, and the rectum; those of the appendix and small tumors seldom metastasize, but reported incidences of metatases from other primary sites and from tumors exceeding 2.0 cm in diameter vary from 25–75%; lymph nodes in the abdomen and the liver may be conspicuously involved, but metastases above the diaphragm are rare. SEE ALSO: carcinoid syndrome. carotid body tumors SYN: chemodectoma. cellular tumors a tumors composed mainly of closely packed cells. cerebellopontine angle tumors SYN: vestibular schwannoma. chromaffin tumors SYN: chromaffinoma. Codman tumors chondroblastoma of the proximal humerus. collision tumors two originally separate tumors, especially a carcinoma and a sarcoma, that appear to have developed by chance in close proximity, so that an area of mingling exists. SEE ALSO: carcinosarcoma. connective tumors any tumors of the connective tissue group, such as osteoma, fibroma, sarcoma. dermal duct tumors a benign small tumors derived from the intradermal part of eccrine sweat gland ducts occurring often on the head and neck. dermoid tumors SYN: dermoid cystumors

desmoid tumors SYN: desmoid (2) . desmoplastic small cell tumors a high-grade malignant tumors found most often in the abdomen of adolescent males; typically tumors cells contain both desmin and keratin, i.e., show hybrid features like fetal mesothelial cells; the exact nature of these cells remains unknown. dysembryoplastic neuroepithelial tumors a rare low-grade neoplasm most frequently seen in children and associated with seizures and cortical dysplasia; the often multinodular, multicystic tumors is composed of oligodendroglial-like cells with accompanying neurons. eighth nerve tumors SYN: vestibular schwannoma. embryonal tumors, embryonic tumors a neoplasm, usually malignant, which arises during intrauterine or early postnatal development from an organ rudiment or immature tissue; it forms immature structures characteristic of the part from which it arises, and may form other tissues as well. The term includes neuroblastoma and Wilms tumors, and is also used to include certain neoplasms presenting in later life, this usage being based on the belief that such tumors arise from embryonic rests. SEE ALSO: teratoma. SYN: embryoma. embryonal tumors of ciliary body SYN: embryonal medulloepithelioma. endocervical sinus tumors malignant germ cell tumors commonly found in the ovary. The tumors arises from primitive germ cells and develops into extra-embryonic tissue resembling the yolk sac. SYN: yolk sac carcinoma. endodermal sinus tumors a malignant neoplasm occurring in the

gonads, in sacrococcygeal teratomas, and in the mediastinum; produces &alpha (α)-fetoprotein and is thought to be derived from primitive endodermal cells. SYN: yolk sac tumors. endometrioid tumors a tumors of the ovary containing epithelial or stromal elements resembling tumors of the endometrium. Erdheim tumors SYN: craniopharyngioma. Ewing tumors a malignant neoplasm which occurs usually before the age of 20 years, about twice as frequently in males, and in about 75% of patients involves bones of the extremities, including the shoulder girdle, with a predilection for the metaphysis; histologically, there are conspicuous foci of necrosis in association with irregular masses of small, regular, rounded, or ovoid cells (2–3 times the diameter of erythrocytes), with very scanty cytoplasm. SYN: endothelial myeloma, Ewing sarcoma. fecal tumors SYN: fecaloma. fibroid tumors old term for certain fibromas and leiomyomas. gastrointestinal autonomic nerve tumors benign or malignant tumors of stomach and small intestine histogenetically related to myenteric plexus; may be familial and related to gastrointestinal neuronal dysplasia. gastrointestinal stromal tumors benign or malignant tumors composed of unclassifiable spindle cells; immunohistochemically distinct from smooth muscle and Schwann cell tumors. giant cell tumors of bone a soft, reddish-brown, sometimes malignant, osteolytic tumors composed of multinucleated giant cells and ovoid or spindle-shaped cells,

occurring most frequently in an end of a long tubular bone of young adults. SYN: giant cell myeloma, osteoclastoma. giant cell tumors of tendon sheath a nodule, possibly inflammatory in nature, arising commonly from the flexor sheath of the fingers and thumb; composed of fibrous tissue, lipid- and hemosiderin-containing macrophages, and multinucleated giant cells. SYN: localized nodular tenosynovitis. glomus tumors [MIM*138000] a vascular neoplasm composed of specialized pericytes (sometimes termed glomus cells), usually in single encapsulated nodular masses that may be several millimeters in diameter and occur almost exclusively in the skin, often subungually in the upper extremity; it is exquisitely tender and may be so painful that patients voluntarily immobilize an extremity, sometimes leading to atrophy of muscles; multiple glomus tumors occur, sometimes with autosomal dominant inheritance. Tumors1 with cavernous spaces lined by glomus cells are called glomangiomas. glomus jugulare tumors a glomus tumors arising from the jugular glomus and usually presenting initially in the hypotympanum. glomus tympanicum tumors a glomus tumors arising on the medial wall of the middle ear. Godwin tumors SYN: benign lymphoepithelial lesion. granular cell tumors a microscopically specific, generally benign tumors, often involving peripheral nerves in skin, mucosa, or connective tissue, derived from Schwann cells; the abundant cytoplasm contains lysosomal granules, the

cells infiltrate between adjacent tissues although growth is slow, and adjacent surface epithelium may show hyperplasia. granulosa cell tumors a benign or malignant tumors of the ovary arising from the membrana granulosa of the vesicular ovarian (graafian) follicle and frequently secreting estrogen; it is soft, solid, white or yellow, and consists of small round cells sometimes enclosing Call-Exner bodies; larger lipid-containing cells may be presentumors SYN: folliculoma (1) . Grawitz tumors old eponym for renal adenocarcinoma. heterologous tumors a tumors composed of a tissue unlike that from which it springs. hilar cell tumors of ovary SYN: steroid cell tumors. histoid tumors old term for a tumors composed of a single type of differentiated tissue. homologous tumors a tumors composed of tissue of the same sort as that from which it springs. innocent tumors SYN: benign tumors. interstitial cell tumors of testis SYN: Leydig cell tumors. islet cell tumors an endocrine tumors composed of cells equivalent or related to those in the normal islet of Langerhans; may be benign or malignant; usually hormonally active; comprises insulinomas, glucagonomas, vipomas, somatostatinomas, gastrinomas, pancreatic polypeptide-secreting tumors, and multihormonal or hormonally inactive pancreatic islet cell tumors. juxtaglomerular cell tumors a tumors of juxtaglomerular cell origin usually presenting with symptoms of secondary aldosteronism, including severe diastolic hypertension, which appears to be due to

tumors-produced renin. The histologic appearance resembles that of a hemangiopericytoma. Klatskin tumors adenocarcinoma located at the bifurcation of the common hepatic ductumors Krukenberg tumors a metastatic carcinoma of the ovary, usually bilateral and secondary to a mucous carcinoma of the stomach, which contains signet-ring cells filled with mucus. Landschutz tumors a transplantable, possibly isoantigenic, highly virulent neoplasm which can be grown in any strain of mice; the host is killed in a few days by what is apparently an anaplastic carcinoma. Leydig cell tumors a testicular and, less commonly, ovarian neoplasm composed of Leydig cells, usually benign but may be malignant; may secrete androgens or estrogens. SYN: interstitial cell tumors of testis. Lindau tumors SYN: hemangioblastoma. low malignant potential tumors SYN: borderline ovarian tumors. malignant tumors a tumors that invades surrounding tissues, is usually capable of producing metastases, may recur after attempted removal, and is likely to cause death of the host unless adequately treated. SEE ALSO: cancer. malignant mixed müllerian tumors (MMMT) SYN: mixed mesodermal tumors. melanotic neuroectodermal tumors of infancy a benign neoplasm of neuroectodermal origin that most often involves the anterior maxilla of infants in the first year of life. It presents clinically as a rapidly growing blue-black lesion producing a destructive radiolucency; histologically, it is

characterized by small, round, undifferentiated tumors cells interspersed with larger polyhedral melanin-producing cells arranged in an alveolar configuration. SYN: melanoameloblastoma, pigmented ameloblastoma, pigmented epulis, progonoma of jaw, retinal anlage tumors. Merkel cell tumors a rare malignant cutaneous tumors seen in sun-exposed skin of elderly patients composed of dermal nodules of small round cells with scanty cytoplasm in a trabecular pattern; the tumors cells contain cytoplasmic dense core granules resembling neurosecretory granules seen in Merkel cells. SYN: primary neuroendocrine carcinoma of the skin, trabecular carcinoma. mesonephroid tumors SYN: mesonephroma. mixed tumors a tumors composed of two or more varieties of tissue. mixed mesodermal tumors a sarcoma of the body of the uterus arising in older women, composed of more than one mesenchymal tissue, especially including striated muscle cells. SYN: malignant mixed müllerian tumors. mixed tumors of salivary gland a tumors composed of salivary gland epithelium and fibrous tissue with mucoid or cartilaginous areas. SYN: pleomorphic adenoma. mixed tumors of skin SYN: chondroid syringoma. mucoepidermoid tumors SYN: mucoepidermoid carcinoma. Nelson tumors a pituitary tumors causing the symptoms of Nelson syndrome. oil tumors SYN: lipogranuloma. oncocytic hepatocellular tumors SYN: fibrolamellar liver cell carcinoma. organoid tumors a tumors of complex structure, glandular in

origin, containing epithelium, connective tissue, etc. Pancoast tumors any carcinoma of the lung apex causing the Pancoast syndrome by invasion or compression of the brachial plexus and stellate ganglion. SYN: superior pulmonary sulcus tumors. papillary tumors SYN: papilloma. paraffin tumors SYN: paraffinoma. phantom tumors accumulation of fluid in the interlobar spaces of the lung, secondary to congestive heart failure, radiologically simulating a neoplasm. phyllodes tumors a spectrum of neoplasms consisting of a mixture of benign epithelium and stroma with variable cellularity and cytologic abnormalities, ranging from benign phyllodes tumors to cytosarcoma phyllodes; most often involves the breastumors pilar tumors of scalp a solitary tumors of the scalp in elderly women that may ulcerate; microscopically resembles squamous cell carcinoma composed of glycogen-rich clear cells, but is benign. SYN: proliferating tricholemmal cystumors Pindborg tumors SYN: calcifying epithelial odontogenic tumors. Pinkus tumors SYN: fibroepithelioma. placental site trophoblastic tumors a tumors usually arising in the uterus of parous women during reproductive years. Histologically, the tumors consists of a predominance of intermediate trophoblastic cells with fibrinoid material and vascular invasion. pontine angle tumors a tumors in the angle formed by the cerebellum and the lateral pons, often refers to an acoustic schwannoma. potato tumors of neck a firm

nodular mass in the neck, usually a carotid body tumors (chemodectoma). pregnancy tumors SYN: granuloma gravidarum. primitive neuroectodermal tumors a designation used to refer to a group of morphologically similar embryonal neoplasms that arise in intracranial and peripheral sites of the nervous system and which may show various degrees of cellular differentiation; includes medulloblastoma, pineoblastoma, etc. ranine tumors SYN: ranula (2) . Rathke pouch tumors SYN: craniopharyngioma. retinal anlage tumors SYN: melanotic neuroectodermal tumors of infancy. Rous tumors SYN: Rous sarcoma. sand tumors SYN: psammomatous meningioma. Sertoli cell tumors a tumors of testis or ovary composed of Sertoli cells; most often benign but may be malignantumors Sertoli-Leydig cell tumors an ovarian tumors composed of Sertoli and Leydig cells; may secrete androgens. SYN: arrhenoblastoma, gynandroblastoma (1) . Sertoli-stromal cell tumors a generic term for ovarian sex-cord stromal tumors composed of Sertoli cells, Leydig cells, and cells resembling rete epithelial cells, either in a pure form or as a mixture of these cell types. solitary fibrous tumors a benign tumors of fibrous tissue which usually arises in the pleural space on other sites. SYN: benign mesothelioma. squamous odontogenic tumors a benign epithelial odontogenic tumors thought to arise from the epithelial cell rests of Malassez; appears clinically as a radiolucent lesion closely associated with the

tooth root and histologically as islands of squamous epithelium enclosed by a peripheral layer of flattened cells. steroid cell tumors a collective term used for ovarian tumors composed of cells resembling steroid-secreting lutein cells; comprises several tumors such as stromal luteoma, Leydig cell tumors, steroid cell tumors not otherwise specified; hormonally active; may be benign or malignantumors SYN: hilar cell tumors of ovary. sugar tumors a benign clear cell tumors of the lung containing abundant glycogen. superior pulmonary sulcus tumors SYN: Pancoast tumors. teratoid tumors SYN: teratoma. theca cell tumors SYN: thecoma. triton tumors a peripheral nerve tumors with striated muscle differentiation, seen most often in neurofibromatosis; named after the Masson theory of transformation of motor nerve fibers into muscle in triton salamanders. turban tumors multiple cylindromas of the scalp which, when overgrown, may resemble a turban. villous tumors SYN: villous papilloma. Warthin tumors SYN: adenolymphoma. Wilms tumors a malignant renal tumors of young children, composed of small spindle cells and various other types of tissue, including tubules and, in some cases, structures resembling fetal glomeruli, and striated muscle and cartilage. Often inherited as an autosomal dominant trait [MIM*194070, *194080, *194090]. SYN: nephroblastoma. yolk sac tumors SYN:

endodermal sinus tumors. Zollinger-Ellison tumors a non–beta cell tumors of pancreatic islets causing the Zollinger-Ellison syndrome."

Secondly, as stated in the MPEP, 2164.08 "[t]he Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation'." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455

(Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination)."

Thirdly, since Applicantrs have no working examples of any tumor treatment in any kind of cell in the specification, why would they believe they possess enablement for treating all the diseases listed above?

Allowable Subject Matter

7. Claims 15-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 14 and 19-27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for after final amendments is (703) 872-9307. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

Mukund Shah
Mukund Shah
Supervisory Patent Examiner
Art Unit 1624

TCMcK
May 27, 2003